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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/615,441	07/07/2003	Jong Soo Ko	2013P095	7432

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EXAMINER

LEVKOVICH, NATALIA A

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 02/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/615,441	Applicant(s) KO ET AL.	
	Examiner Natalia Levkovich	Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07/07/2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07/07/2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being unclear for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 does not set forth structural cooperation between elements of sensing substrate and elements of channel substrate, therefore Claim 1 is indefinite.

Claims 2 and 3 are indefinite, since they do not recite further structural limitations to the device of Claim 1.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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4. Claims 1-4 are rejected under 35 U.S.C. 102(b) as anticipated by Hui Liu et al. (PG PUB 20040007275).

Hui Liu discloses an integrated bio-microfluidic analytical device comprising a fluidic cartridge ['channel substrate'- examiner] and a printed circuit board / PCB ['sensing substrate'- examiner] bonded together. The fluidic cartridge comprises a hybridization buffer storage chamber, a PCR chamber, a hybridization detection chamber coupled by fluid communication channels, inlet and outlet ports. The PCB includes temperature sensors, heaters, detection electrodes with DNA capture probes, required circuits ['electrode interconnect'- examiner], and contacts for electronic connection ['electrode pad'- examiner]. [0014], [0026]. Fluids flow can be manipulated by gravity, or by pump, or by capillary forces. Sample and reagents are loaded into the device into separate chambers, indicating at least two inlet ports (See [0016], [0017], [0033], [0034], [0039], claims 2-3).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 5-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hui Liu et al. (PG PUB 20040007275) in view of Troian et al. (PG PUB 20020150683).

Hui Liu does not disclose hydrophilic and hydrophobic materials and their combinations. Troian teaches methods of fluid routing and mixing in biosensors and other microfluidic applications. The fluid pathways and other elements of the device are patterned with areas having hydrophobic or hydrophilic properties, in order “to produce surfaces of mixed wettability” ([0012], [0049], [0053], [0056].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have employed hydrophilic / hydrophobic materials in the modified apparatus of Hui Liu, in order to enhance control over fluid flow.

With respect to claim 9, Hui Liu teaches a plurality of heaters in his bio-detector, as was discussed above. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have employed micro-heaters to warm any part of the device necessary for accurate detection.

8. Claims 10-14 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hui Liu et al. (PG PUB 20040007275) in view of Blackburn et al. (PG PUB 20030190608).

Hui Liu does not disclose capillary stops. Blackburn et al. disclose devices which comprise flow-through biochannels including a plurality of capture binding ligands. The

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fluid flow control systems of the device “can comprise capillary stop valves. In the capillary stop valve approach, a discontinuity in the channel, such as an abrupt decrease in channel cross-section or the presence of a hydrophobic region, substantially prevents the passage of fluid until a sufficiently high pressure is applied” [0335], [0372], [0373], [0412]. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have employed capillary stops in the modified the apparatus of Hui Liu, in order to provide flexible flow control of the fluids.

With regards to claims 10 and 20, Hui Liu does not specify means of bonding the substrates together. Blackburn teaches that adhesives can be used to assemble the layers of the device together, as well as laminating and mechanical means of bonding and alignment ([0329], [0133]-[0145]). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have employed adhesive materials and mechanical means, for example, grooves, protrusions, clamps, etc., in the modified apparatus of Hui Liu, in order to bond substrates together.

9. Claims 15-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hui Liu et al. (PG PUB 20040007275) in view of Blackburn et al. (PG PUB 20030190608) and further in view of Troian et al. (PG PUB 20020150683).

Hui Liu modified by Blackburn does not disclose hydrophilic and hydrophobic materials and their combinations. Troian teaches methods of fluid routing and mixing in biosensors and other microfluidic applications. The fluid pathways and other elements of the device are patterned with areas having hydrophobic or hydrophilic properties, in order “to produce surfaces of mixed wettability” ([0012], [0049], [0053], [0056].

It would have been obvious to one of ordinary skill in the art at the time the

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invention was made to have employed hydrophilic / hydrophobic materials in the modified apparatus of Hui Liu, in order to enhance control over fluid flow.

With respect to claim 19, Hui Liu modified by Blackburn teaches a plurality of heaters in his bio-detector, as was discussed above. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have employed micro-heaters to warm any part of the device necessary for accurate detection.

Conclusion


10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: PG PUB 2003/0083685.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalia Levkovich whose telephone number is 571-272-2462. The examiner can normally be reached on Mon-Fri, 8 a.m.-4p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Jill Warden
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Technology Center 1700